Pain Physician. 2005;8:271-276, ISSN 1533-3159

A Prospective Case Series

Treating Radiculopathy with an Indwelling Epidural Catheter and Infusion Pump

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Background: For the purpose of reducing inflammation causing radiculopathy, lumbar transforaminal and interlaminar epidural injections deliver corticosteroid to the vicinity of the spinal nerve, nerve roots, and intervertebral disc. Although acceptable, the efficacy of transforaminal injections is limited and variable. An indwelling epidural catheter offers the distinct advantages of delivering greater concentrations of corticosteroid directly to the site of pathology, over an extended duration. This extended exposure to corticosteroid may benefit the site of pathology.

Objective: To evaluate the safety and efficacy of corticosteroid administered through a disposable indwelling epidural catheter and infusion pump to treat pain and dysfunction caused by lumbosacral radiculopathy.

Study Design: A pilot investigation consisting of a prospective consecutive series of 10 patients, conducted in a specialty hospital.

Methods: An indwelling epidural catheter dispensed corticosteroid into the epidural space at the suspect level of pathology. The catheter was attached to an external, lightweight, spring-pressurized, and disposable reservoir pump holding 8.0 mg dexamethasone diluted with bacteriostatic normal saline to a total volume of 72 ml. After each patient's hospital discharge, the medication was administered into the epidural space at a rate of 1 ml per hour over a 72-hour period. Follow-up at six weeks was achieved in 100% of the patients.

Outcome measures: The outcome measures, recorded at pre-treatment and six weeks post-treatment were assessed using: the Visual Analog Scale (VAS); MOS 36-Item Short-Form Health Survey (SF-36); Pain Symptoms Survey; Oswestry Disability Index; Beck Inventory; Work History Survey; Work Index; Expectations Met Survey; Activities of Daily Living Form; and the Satisfaction With Treatment Form.

Results: There was no patient morbidity or mortality associated with this treatment, and patients, on average, experienced decreased pain levels after treatment. Mean delta VAS improvement was 4.1 (SD = 2.6, R =-9.6 to +1.5). The mean percent improvement was 46.7%.

Conclusions: Safe and effective treatment of lower extremity radiculopathy symptoms may be obtained with this new method.

Keywords: Lumbar spine, radiculopathy, indwelling epidural catheter, pump, corticosteroid

The first description of an "epidural" injection of corticosteroid described delivery through the S-1 posterior sacral foramen (1), which ultimately became the preferred method of treatment (2-9). Subsequently, this practice style slowly changed to bias epidural injections utilizing the caudal and interlaminar approaches (10-15). Subsequent reviews of the initial investigations (16-19), and comparisons to more recent controlled trials, revealed that epidural corticosteroids administered through interlaminar and caudal routes were less effective than initially claimed.

Investigators suggested that epidural corticosteroids might possess greater efficacy if they were delivered in a more exact fashion to the presumed site of pathology (20-23). Therefore, over time, transforaminal injections of corticosteroid evolved as the preferred route to treat radicular pain. This practice was kindled by reports of successful outcomes in observational studies, and later by the results of controlled trials.

These observations, coupled with the desire for increased efficacy, causes contemporary doctrine to favor administering medication directly onto the site of pathology by the transforaminal approach instead of the interlaminar or caudal approach (24-27). Unfortunately, because the corticosteroid is typically administered as a single bolus, both the maximum allowable dose and the duration of exposure to the medication remain limited.

Experimental evidence suggests that inflammatory processes cause the symptoms patients experience when lumbar spinal nerves and nerve roots are affected by intervertebral disc herniations (28-43). Corticosteroids suppress this inflammation, thus relieving the symptoms. Controlled trials (20-23) demonstrate greater efficacy when placing corticosteroid immediately proximal to the affected perineural tissue instead of in the general epidural area; thus logic dictates that directly bathing the affected spinal nerve, nerve root, and adjacent epidural tissue with corticosteroid over a prolonged period may serve to suppress inflammation and minimize symptoms.

Recall that injecting a single bolus of corticosteroid mandates that the maximum allowable dose, and the duration of exposure to the medication, both remain limited. To address that limitation, an indwelling epidural catheter offers the distinct advantage of delivering maximum concentrations of medication directly to the site of pathology, over an extended

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Disclaimer: There was no external funding in preparation of this manuscript.
Conflict of Interest: Michael L. Shapiro, MD, is the inventor and owner of Infusion Catheter Epidural.
Manuscript received on 4/25/2005
Revision submitted on 6/15/2005
Accepted for publication on 6/21/2005

duration.

Because only one procedural encounter in a fluoroscopy facility is necessary for the performance of this procedure, it may offer cost effectiveness when compared with other contemporary treatments (32).

Methods

Patient Selection

The study was approved by the institutional review board of the Texas Spine and Joint Hospital, Tyler, Texas. The objective was to test the efficacy and safety of an indwelling epidural catheter dispensing corticosteroid to treat radiculopathy. Between August 2004 and December 2004, patients for the study were recruited from the practice of the senior investigator. Interested patients who appeared eligible attended a face-to-face interview and physical examination to confirm their eligibility. Patients enrolled in this trial were to have experienced unilateral lower extremity radicular pain that occurred for longer than six week's duration and with intensity greater than six points out of 10 on the visual analogue scale (VAS). They must have had a positive straight leg raise test (Lasègue Sign) of between 20 degrees and 70 degrees from the horizontal plane. In some instances, electrodiagnostic signs of radiculopathy reinforced the diagnosis, but were not a prerequisite for inclusion. The target level to be treated was determined on the basis of the distribution of the patient's signs and symptoms, and on consideration of imaging studies, if these were available.

Other eligibility criteria were: patient age between 18 and 65 years; failure to improve following at least six weeks of non-operative care including anti-inflammatory and analgesic medications, and a physical therapy and/or home directed lumbar exercise program. Several subjects had failed to experience sustained relief with prior fluoroscopically-guided transforaminal injections of corticosteroid.

Exclusion criteria included: sequestered intervertebral disc herniations; concomitant cervical or thoracic pain greater than two out of 10 on the VAS; uncontrolled or acute medical illness; chronic severe conditions such as rheumatoid arthritis; ambulatory dysfunction; and unwillingness to consent to the study. Additionally, patients were also excluded if they had any of the following: a known anaphylactic reaction to contrast medium; demonstrated evidence of localized infection in the procedural field; a systemic infection; immunosuppression; bleeding diathesis or concurrent use of anticoagulants; pregnancy; or the potential for secondary gain including workmen's compensation, litigation, or disability.

Equipment

Components of the disposable indwelling epidural catheter and pump system used included: a 100 ml medication reservoir with a carrying pouch and Velcro belt attachment; a 17-inch length of medication tubing; a 5 micron medication filter and flow regulator (Sgarlato Labs); an 18-gauge introducer needle; and a 100 cm, 20-gauge radiopaque tipped medication catheter (Epimed).

Technique

After informed consent was obtained, the patient's posterior thoracic and lumbosacral skin was aseptically prepared and appropriately draped. The skin was anesthetized with 1.5% lidocaine, 1-5 segments rostral to the suspect segment. Employing an interlaminar approach in an atypical cephalad to caudad trajectory, the tip of a 3.5-inch, 18-gauge introducer needle was directed into the epidural space with loss of resistance technique; appropriate epidural placement was confirmed by radiographic observation of injected radiopaque contrast medium (Isovue 300). A 20-gauge spinal catheter was directed through the introducer needle and navigated in a caudal direction towards the suspect affected segment (Figure 1). Radiopaque contrast medium was again injected to confirm appropriate placement. Following confirmation, a bolus of 2 ml of 1.5% lidocaine and 2 ml of 4.0 mg/ml dexamethasone was injected through the catheter before securing it to the skin with an adhesive patch and connecting it to the infusion pump. Within the reservoir was 8.0 mg dexamethasone diluted with bacteriostatic normal saline to a total volume of 72 mL. The pump was pre-set to administer 1 ml of injectate per hour over the ensuing 72-hour period, and subjects were discharged to home following 30 minutes of monitored recovery.

Statistical Analysis

The authors used the Statistical Analysis System statistical package (Version 8.2: SAS Institute, Cary, NC) for all statistical analyses. Patients served as their own control; a paired t-test was used to compare outcomes from baseline to a follow-up visit. The VAS, Oswestry, and SF-36 scores from baseline to a follow-up visit were analyzed. Results are reported as the mean (standard deviation).

Results

Outcome tools were administered by a registered nurse and medical doctor and recorded at zero, three days, and six weeks. Tools included: the VAS (44-48); SF-36 (49-51); Pain Symptoms Survey; Oswestry Disability Index (52); Beck Inventory; Work History Survey; Work Index; Expectations Met Survey; Activities of Daily Living form; and the Satisfaction with Treatment forms.

For continuous variables, group means and standard deviations were determined and compared using a t-test. The primary objective of the study was to compare the improvement in pain and physical function before and after treatment. Secondary objectives included reporting the adverse event profile of an indwelling epidural catheter and functional outcomes as measured in the SF-36. For each patient, the percentage of pain relief at follow-up was calculated as the difference between their pain score from baseline, divided by their baseline score, and converted to a percentage.

Ten patients agreed to enroll in this trial, and all underwent treatment. All

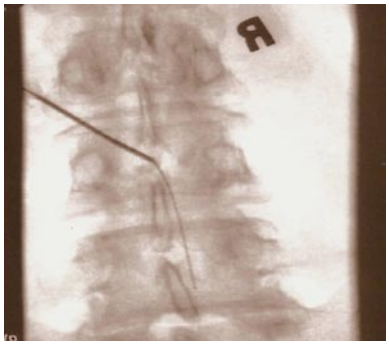

Fig. 1. Anterior-Posterior plain film radiograph, prior to radiopaque contrast injection, demonstrating introducer needle directed into the right L3-L4 intervertebral space with catheter advanced caudally to treat a right L-5 radiculopathy.

ten subjects completed the pre-treatment outcome tools and the post-treatment outcome tools at three days and greater than six weeks post procedure. One patient experienced worsening of her symptoms and one remained unchanged, the remaining eight patients experienced improvement of symptoms. The mean pre-treatment VAS score was 8.1 (SD = 1.2; R = 7-10). The mean post-treatment VAS score was 4.1 (SD = 2.6; R = 0.4-8.5). The mean change of pain score was 4.1 (SD = 2.6; R = -9.6-1.5). The overall mean improvement based on the VAS score was 49.4% (Table 1). Subjects exhibited statistically significant improvements in mean VAS pain scores, the eight domains of the SF-36, and Oswestry Disability Scale (Tables 2 and 3)t.

Discussion

While conducting this study, it was evident that many patients were reluctant to volunteer. Among other factors, it is likely that the ready availability of a known treatment lessened the likelihood of patient participation (53, 27). Others (54-55) have reported similar problems when initiating trials of new or controversial treatments for low back or radiculopathy pain. In the present context, epidural injections were readily available from other sources in conventional practice. This limited the population from which the present sample could be drawn. Patients did not need to participate in a trial if they could obtain the treatment elsewhere. Additionally, patients with compensation claims were deliberately excluded in order to avoid potentially confounding effects of litigation. As a result, the sample obtained was not representative of what might be considered the typical patient with chronic low back and radiculopathy pain.

Nevertheless, the sample was appropriate for the nature of this study, which was an explanatory pilot trial to test the technique, in addition to the safety and efficacy, of employing an indwelling epidural catheter and infusion pump to treat radiculopathy. For that purpose, the critical eligibility criterion was that the patients had the correct indication for the procedure, which the present sample satisfied.

Follow-up was achieved at six weeks in 100% of patients enrolled in the study. Furthermore, since the study was designed as an explanatory study, a six-week follow-up was judged sufficient to test for statistically significant differences. Six weeks was chosen since it has been shown that after six weeks the results of epidural injections are fairly stable, although six-week outcomes may not be predictive of long-term outcomes.

The principal findings of the study were that the treatment achieved a statistically significant improvement in mean pain scores when compared to the baseline scores. Similarly, SF-36 outcome tools demonstrated improvement.

In this pilot investigation, the epidural catheter and pump technique did not prove to be a universally successful treatment. Twenty percent of the patients did not benefit appreciably, or at all. This feature dilutes mean scores on outcome measures. The incidence of deterioration in pain levels was low.

Each of the ten patients studied had not responded to a regimen of conservative care that included bed-rest, drug therapy, or physical therapy. Two patients had experienced brief significant relief with prior transforaminal injections of lidocaine and corticosteroid, but failed to ex-

Table 1. Full analysis of base line outcome measures of patients assigned to undergo treatment

Pre-treatment Outcome Measures	Mean ± SD
VAS for pain (0-10)	8.1 ± 1.2
SF-36 (0-100)	
Bodily Pain	23.5 ± 20.7
Physical Functioning	27.5 ± 23.2
Role Physical	5.0 ± 15.8
Role Emotional	20.0 ± 35.8
Social Functioning	36.3 ± 26.0
Mental Health	56.8 ± 20.3
General Health	51.0 ± 20.1
Vitality	25.0 ± 16.5
Oswestry Disability Scale (0-100)	50.1 ± 10.0

Table 2. Main outcomes of patients who underwent treatment (the P values pertain to paired t-tests)

Outcome Measure (n = 10)	**Pre-treatment**	**6 weeks**	**Change**	***P* Value**
VAS for pain (0-10)	8.1 ± 1.2	4.1 ± 1.2	4.0 ± 3.6	<0.01
SF-36: Bodily Pain (0-100)	23.5 ± 20.7	72.5 ± 16.1	49.0 ± 27.6	<0.01
SF-36: Physical Functioning (0-100)	27.5 ± 23.2	73.9 ± 15.5	46.4 ± 28.2	<0.01
Oswestry Disability Scale (0-100)	50.1 ± 10.0	20.4 ± 20.0	-29.7 ± 18.6	<0.01

perience sustained relief, yet in the study they experienced appreciable benefit with an indwelling catheter. In this study, one of the subjects of the investigation ultimately underwent a surgical discectomy.

By comparison, in a transforaminal investigation, Weiner and Fraser (56) reported that six of their 30 patients later had surgery. Two of their patients were lost to follow-up but had reported complete relief of their pain at six weeks after injection. Of the remaining 22 patients, 14 had complete relief of pain at an average follow-up of three years (range: 1-10 years); seven patients had moderate relief of pain. These figures represent a 46% success rate in achieving complete relief of pain with a transforaminal approach.

Lutz et al (57) reported that 52 of their 69 patients (75%) achieved greater than 50% reduction in their pain, at 28-144 weeks follow-up. They did not report how many patients achieved complete relief of pain.

These and other studies evidence the fact that transforaminal injections don't provide a universal cure for lumbar or sacral radiculopathy pain, but suggest that they constitute a clinically and statistically worthwhile option before embarking on surgery. In those studies, 46% of patients obtained complete relief, and 75% of patients obtained greater than 50% pain, thus precluding their need for surgery (57).

Various factors may account for differences in the outcomes between this pilot trial and other prior studies. The various cohorts may differ in psychosocial domain, the severity of disability, and where they fall within the timeframe of their illness. Additionally, health care providers may express different non-specific effects of treatment, and endorse different selection criteria.

In the present study, one patient subsequently experienced worsening radiculopathy symptoms prior to the six-week endpoint. Closer scrutiny of her MRI which was obtained prior to her treatment, demonstrated a small, extruded disc fragment that was initially unidentified. This criterion could allow the formal exclusion of her participation in this trial, and allow her outcomes to be removed from the group, based on Federal Drug Administration regulations (55). If this one outlier is censored, this changes the mean pain scores at six weeks, improving the mean pain relief and overall strength of this treatment. However, while drawing attention to this possible concession, the authors have chosen not to rely on it for drawing conclusions concerning the relative efficacy of this treatment. Additionally, this patient was not excluded because one cannot necessarily conclude that the treatment failure was due to the disc fragment. Failure may have been due to the overall limited efficacy of the treatment, and to exclude the subject would be an unfair bias.

The reader must also entertain the possibility that symptom improvement could be the result of regression to the norm; relief experienced independent of the treatment provided. A concurrent control group for comparison would serve well to determine the likelihood of that possibility, although historical control groups suggest that this is not the case. However, the methods used addressed the concerns of this pilot investigation.

Table 3: Pre and Post SF-36 eight domain scores

SF-36 Domains Measures	Baseline	6 weeks	Change	*P* Value
Physical functioning	27.5 ± 23.2	73.9 ± 15.5	46.4 ± 28.2	<0.001
Role physical	5.0 ± 15.8	47.5 ± 43.2	42.5 ± 42.6	0.012
Role emotional	20.0 ± 35.8	60.0 ± 37.8	40.0 ± 49.2	0.030
Vitality	25.0 ± 16.5	67.5 ± 12.7	42.5 ± 24.1	<0.001
Mental health	56.8 ± 20.3	82.4 ± 4.3	25.6 ± 21.2	0.004
Social functioning	36.3 ± 26.0	79.0 ± 19.1	42.8 ± 24.3	<0.001
Bodily pain	23.5 ± 20.7	72.5 ± 16.1	49.0 ± 27.6	<0.001
General health	51.0 ± 20.1	75.2 ± 18.9	24.2 ± 23.5	0.009

Conclusion

While affording satisfactory symptom relief with comparatively few surgical facility encounters, administering corticosteroid through an indwelling epidural catheter over three days may be a viable treatment option for radicular pain.

Acknowledgements

The authors acknowledge the staff of the Texas Spine and Joint Hospital in Tyler, Texas, and Spine Specialists for their support of this investigation.

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